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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/783,291	02/19/2004	Edward H. Overstreet	05-00643-02	6152

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ADVANCED BIONICS, LLC
IP Dept. - Bryant Gold
28515 Westinghouse Place
VALENCIA, CA 91355

EXAMINER

BOCKELMAN, MARK

ART UNIT	PAPER NUMBER
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3766

NOTIFICATION DATE	DELIVERY MODE
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12/08/2009

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No. 10/783,291	Applicant(s) OVERSTREET, EDWARD H.	
	Examiner Mark W. Bockelman	Art Unit 3766	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 October 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 10-17 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 10-17 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|-------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendment

Applicant's request for reconsideration of the finality of the rejection of the last Office action is persuasive and, therefore, the finality of that action is withdrawn. The after final amendment dated 10-12-2009 has been entered and the following grounds of rejection are applied. Because the claims remaining in the case were amended in the response of 3-12-09, all grounds of rejections applied now could have been applied in the office action mailed 7-10-09 and been properly made final. Thus this office action is in response to that amendment and is properly made final as necessitated by that amendment.

Specification

Claims 10-17 are objected to because of the following informalities: Claims 10-17 use means plus function language with no corresponding antecedent basis in the specification for the means plus function language. Appropriate correction is required. In accordance, with MPEP 2181 IV, and in part because of the confusion describe below, the examiner **REQUIRES** applicant to amend there specification to identify each "means plus function" structural element by their corresponding "means plus function" claim clause language.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 10-17 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 10 as amended in the amendment of 3-12-2009 lists various means plus function elements as well as a differential amplifier. In applicant's arguments on page 7 of the response dated 10-12-2009, applicant argued that the "means for recording" recited in the claim requires the use of a differential amplifier and that the examiner must show a differential amplifier or equivalent. Since the claim already recited one differential amplifier in line 3 of the claim, then, according to applicant's arguments, there are now two differential amplifiers being recited. Nowhere in applicant's specification is the description of an embodiment using two differential amplifiers found. Moreover, the claim as now written seems to embrace two different disclosures of inventions. In paragraph [0042] of applicant's specification many of the features claimed in claim 10 such as charge determination element are said to be taught in US patents 6,219,580, 6,487,453 and 6,516,227 (notably applied by the examiner in the last office action). In paragraph [0044] of applicant's specification, another system is mentioned that uses a differential amplifier, specifically CII Bionic EarTM. However the other elements that are recited in applicant's claims, which were only described as elements of the patents mentioned (i.e. paragraph [0042]), are not mentioned in connection to the CII Bionic EarTM device. In addition, a trademark does not

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define specific elements but instead is subject to change rendering the elements to indefiniteness. Thus it is unclear if this device possesses any or all of those elements any whether any particular elements are associated therewith.

Furthermore, there is no suggestion to combine these known inventions and even less information concerning how to so. In sum, it is unclear how or where applicant is drawing support for the invention as now claimed.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 10-17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Applicant's claims are indefinite in that it is unclear which structure is being covered under each of the means plus function clauses. As an example, applicant's claim 10 recites a "differential amplifier" in line 3. However, applicant additionally argues that a differential amplifier is included in the "means for recording" limitation. This constitutes a device claim in which it can be read to include the same element twice. MPEP 2173.05 (o). This results in indefiniteness to the claim under both double inclusion and improper use of means plus function language.

Moreover, applicant's claims seem to correspond to a hybrid of two inventions disclosed in the specification (as noted above) which was never described in adequate terms or relying upon a trademark to define specific elements which a trademark does not. It is unclear what claimed elements

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correspond to which, if any of the disclosed elements (embodiments) which additionally renders the claims indefinite.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 10-17 are rejected under 35 U.S.C. 102(b or e) as being anticipated by CII Bionic Ear™ device by Advanced Bionics Corporation. Applicant's only disclosure of a device using a differential amplifier is in connection with the CII Bionic Ear™ device found in paras. [0044] to [0045] of applicant's specification. To the extent applicant is relying upon the CII Bionic Ear™ device for claim support, the known trademark (device) anticipates the claims. The examiner requests a copy of all known documentations, including the inventors of the various embodiments of this trademark (device) and when it was available to the public, in response to this office action. This system seems to

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have been made available to the public at least as early as its FDA approval in March of 2001 according to various websites.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 10-11, 16 -17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Meadows et al USPN 6,516,227 in view of King USPN 5,702,429. Meadows teaches a system for measuring and setting stimulation levels in a spinal chord stimulation device. Threshold measurements may be taken by clinician programmer (column 5 lines 65-67) which are measure in terms of amplitudes The pulse width may also be set in groups (column 35, lines 5-20). Thus each electrode will receive the same charge. To have set amplitude and pulse width to a value within the range above the lowest measured electrode threshold would be inherent to the device and method as a result of the choice of range. The Meadows reference is listed as devices that are covered by applicant's means plus function language in para [0042] of applicant's specification and thus meet applicant's means plus function elements. Although a differential amplifier is not specified, such would be an obvious inclusion for measuring compound action potentials as seen in King USPN 5,702,429.

Claims 12-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Meadows et al USPN 6,156,227 in view of King USPN 5,702,429 as applied to claims 10-11, 16 -17 above, and further in view of WO 01/43818 or Franck et al "Estimation of Psychophysical Levels Using the Electrically evoked compound action potential measured with the Neural Response Telemetry Capabilities of Cochlear Corporations CI24M Device. Applicant's dependent claims differ from Meadows in the mapping and determination of threshold levels using multiple stimuli. To have modified the Meadows application to include such techniques for determining the threshold levels that Meadows seeks would have been obvious. Applicant's disclosed means seem to correspond to the structures of Meadows (para. [0042]) and WO 01/43818 (para [0004]).

Claims 10-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kuzma et al. USPN 6,487,453 or Faltys et al USPN 6,219,580 USPN 6,219,580, either in view of CII Bionic EarTM device by Advanced Bionics Corporation or King USPN 5,702,429. According to applicant's specification at paragraph [0042], the recited "implantable neural stimulation system may be realized using a hardware and software/firmware platform as described above in connection with 1A, and also described, e.g. in US Patent Numbers 6,219,580; 6,487,453 and 6,516,227, which patents are hereby incorporated by reference". Presumably all the elements including means plus function limitations are described in these patents since no other circuitry or means is adequately

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described elsewhere in the specification. Applicant differs in reciting a differential amplifier in the claims. Using a differential amplifier for recording compound action potentials was known in the art as evidenced by applicant's statements in paragraph [0044] of his specification concerning CII Bionic Ear™ device by Advanced Bionics Corporation. To the extent that applicant has formulated a claimed invention by combining two separate disclosures from their specification with no suggestion to do so and even less details on how to do so, it would have likewise been obvious to modify the 6,219,580; 6,487,453 and 6516227 patents with CII Bionic Ear™ device by Advanced Bionics Corporation or King USPN 5,702,429 teachings since merely selecting features from related patents to formulate other embodiments using the desired features is conventional design.

Response to Arguments

Applicant's arguments filed 10-12-2009 have been fully considered but they are not persuasive. Applicant's arguments are based upon the use of means plus function language incorporated in the claim. Notably, these are the first arguments concerning the invocation of such language. Thus, the examiner has turned to applicant's specification to determine the scope of the elements. The examiner first notes that as stated above, the particular elements corresponding to the means plus function cannot be ascertained from applicant's specification and moreover, appear to be a mixing of embodiments at least upon the current reading of the specification since the only use of means is in connection with. In addition, if applicant is relying upon a trademark to define the invention in a

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means plus function format, such is subject of indefiniteness by its very nature since the elements are subject to change. Notwithstanding, the known device anticipates the claims.

Applicant has additionally focused in on the use of a differential amplifier and argued special qualities surrounding the use of such. The examiner is unaware of any particular unexpected quality of the simple use of a differential amplifier to measure electrical signals emanating from a patient. Perhaps applicant's arguments have more to do with the specific detection system within an embodiment of the CII Bionic trademark which applicant now attempts to patent. Nevertheless, the examiner has supplied a secondary reference in King 5,702,429 showing the use of a differential amplifier for detecting and recording compound was well known in the art and to have modified the Meadows to have included the King detection system including the differential amplifier would have been obvious.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be

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calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark W. Bockelman whose telephone number is (571) 272-4941. The examiner can normally be reached on Monday - Friday 8:00 - 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Carl Layno can be reached on (571) 272 -4949. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Mark W Bockelman/

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Primary Examiner, Art Unit 3766

December 2, 2009